Complete Summary

GUIDELINE TITLE

Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain.

BIBLIOGRAPHIC SOURCE(S)

Manchikanti L, Staats PS, Singh V, Schultz DM, Vilims BD, Jasper JF, Kloth DS, Trescot AM, Hansen HC, Falasca TD, Racz GB, Deer TR, Burton AW, Helm S, Lou L, Bakhit CE, Dunbar EE, Atluri SL, Calodney AK, et al. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. Pain Phys 2003;6:3-81. [1175 references]

COMPLETE SUMMARY CONTENT

SCOPE

DISEASE/CONDITION(S)

Chronic spinal pain

GUIDELINE CATEGORY

Diagnosis
Management
Treatment

CLINICAL SPECIALTY

Anesthesiology
Emergency Medicine
Family Practice
Internal Medicine

Neurological Surgery
Neurology
Orthopedic Surgery
Physical Medicine and Rehabilitation
Radiology
Rheumatology

INTENDED USERS

Advanced Practice Nurses
Health Plans
Managed Care Organizations
Physician Assistants
Physicians
Utilization Management

GUIDELINE OBJECTIVE(S)

- To assist both physicians and patients in making decisions about appropriate health care in the diagnosis and treatment of chronic or persistent pain
- To improve quality of care, improve patient access, improve patient outcomes, improve appropriateness of care, improve efficiency and effectiveness, and achieve cost containment by improving the cost-benefit ratio

TARGET POPULATION

All patients suffering with chronic spinal pain who are eligible to undergo commonly utilized and effective interventional technique(s)

INTERVENTIONS AND PRACTICES CONSIDERED

Diagnostic Interventional Techniques

1. Facet joint diagnostic blocks
2. Provocative discography
3. Transforaminal epidural injections
4. Sacroiliac joint blocks

Therapeutic Interventional Techniques

1. Facet Joint Pain
    - Intraarticular injections
    - Medial branch blocks
    - Medial branch neurotomy
2. Epidural injections
    - Caudal epidural injections
    - Interlaminar epidural injections
    - Transforaminal epidural injections
3. Epidural adhesiolysis
4. Intradiscal therapies

- Intradiscal electrothermal therapy
- Nucleoplasty

5. Implantable therapies
    - Spinal cord stimulation
    - Implantable intrathecal drug administration system

MAJOR OUTCOMES CONSIDERED

- Validity, specificity, and sensitivity of diagnostic interventions for spinal pain
- Patient's quality of life
- Patient's mood, activities of daily living
- Effectiveness of treatment in controlling pain (i.e., short-term and long-term pain relief)
- Complications of therapy
- Patient-reported pain intensity as recorded with standard pain scales
- Associated costs (e.g., healthcare expenditures, disability compensation, lost production, lost tax revenue)

METHODOLOGY

METHODS USED TO COLLECT/SELECT EVIDENCE

Hand-searches of Published Literature (Primary Sources)
Hand-searches of Published Literature (Secondary Sources)
Searches of Electronic Databases

DESCRIPTION OF METHODS USED TO COLLECT/SELECT THE EVIDENCE

The search strategy utilized for evidence synthesis was comprehensive and included an extensive search of Index Medicus and EMBASE; all relevant and published peer-reviewed indexed and nonindexed journals; scientific meeting proceedings, scientific newsletters; and cross references from articles, systematic and narrative reviews. In the analysis of evidence, systematic reviews, randomized clinical trials, observational reports and diagnostic test studies were utilized. A separate search strategy was designed for each subject under investigation. The inclusion and exclusion criteria as shown in Table 2 (in the original guideline document) were utilized.

All systematic reviews, randomized trials, prospective trials; retrospective evaluations with at least 50 patients, and abstracts presented in the past 2 years were utilized, if criteria were met.

NUMBER OF SOURCE DOCUMENTS

Over 1,500

METHODS USED TO ASSESS THE QUALITY AND STRENGTH OF THE EVIDENCE

Weighting According to a Rating Scheme (Scheme Given)

RATING SCHEME FOR THE STRENGTH OF THE EVIDENCE

Designation of Levels of Evidence

Level I

Conclusive: Research-based evidence with multiple relevant and high quality scientific studies or consistent reviews or consistent reviews of meta-analyses.

Level II

Strong: Research-based evidence from at least one properly designed randomized, controlled trial of appropriate size (with at least 60 patients in the smallest group); or research-based evidence from multiple properly designed studies of smaller size; or at least one randomized trial, supplemented by predominantly positive prospective and/or retrospective evidence.

Level III

Moderate: Evidence from a well-designed small randomized trial or evidence from well-designed trials without randomization, or quasi-randomized studies, single group, pre-post cohort, time series, or matched case-controlled studies or positive evidence from at least one meta-analysis.

Level IV

Limited: Evidence from well-designed nonexperimental studies from more than one center or research group.

Level V

Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees.

METHODS USED TO ANALYZE THE EVIDENCE

Review of Published Meta-Analyses
Systematic Review with Evidence Tables

DESCRIPTION OF THE METHODS USED TO ANALYZE THE EVIDENCE

Table 3 of the original guideline illustrates important domains and elements for systems to rate the quality of systematic reviews, randomized clinical trials, observational studies and diagnostic test studies. Four types of quality evaluation forms obtained and modified from the Agency for Healthcare Research and Quality (AHRQ) and Manchikanti et al have been utilized for each quality evaluation of systematic review(s), randomized controlled trial(s), observational evaluation(s) and diagnostic test(s). All systematic reviews randomized trials, prospective trials; retrospective evaluations with at least 50 patients, and abstracts presented in the past 2 years were utilized, if criteria were met.

METHODS USED TO FORMULATE THE RECOMMENDATIONS

Expert Consensus

DESCRIPTION OF METHODS USED TO FORMULATE THE RECOMMENDATIONS

Recommendations were based on strength of evidence of moderate or higher, derived from analysis of the literature. When at least moderate evidence was not available, it was based on consensus and was identified in the algorithm as "not based on evidence synthesis."

RATING SCHEME FOR THE STRENGTH OF THE RECOMMENDATIONS

Not applicable

COST ANALYSIS

Descriptions of the review of published cost analyses are provided in the body of the guideline for each interventional technique in subsections called "Cost Effectiveness."

METHOD OF GUIDELINE VALIDATION

Peer Review

DESCRIPTION OF METHOD OF GUIDELINE VALIDATION

Not stated

RECOMMENDATIONS

MAJOR RECOMMENDATIONS

These recommendations are presented in abbreviated form. Readers should refer to the text of the guideline document for a detailed discussion of each of the following topics.

Definitions for the designations of levels of evidence (level I [conclusive], level II [strong], level III [moderate], level IV [limited], and level V [indeterminate]) are given at the end of the Major Recommendations.

Diagnostic Interventional Techniques

Facet Joint Diagnostic Blocks

Based on multiple evaluations, the validity, specificity and sensitivity of facet joint nerve blocks are considered strong in the diagnosis of facet joint pain. Based on multiple evaluations, facet or zygapophysial joints have been implicated as the source of chronic spinal pain in 15% to 45% of the heterogenous groups of

patients with chronic low back pain, 48% of the patients with thoracic pain, and 54% to 67% of the patients with chronic neck pain. Reported false-positive rates varied from 27% to 63% in cervical spine, 58% in thoracic spine, and 22% to 47% in lumbar spine.

Provocative Discography

Extensive evidence of provocative discography was reviewed on normal volunteers, comparison of discography findings on post mortem specimens, comparison with computed tomography and magnetic resonance imaging, high-intensity zone identification, evidence of discogenic pain or internal disc disruption and false-positives in patients with low back pain or with psychological abnormalities. Based on the cumulative analysis of the literature, the evidence for cervical and thoracic discography is limited. However, the evidence for lumbar discography is strong for discogenic pain provided that lumbar discography is performed based on the history, physical examination, imaging data, and analysis of other precision diagnostic techniques. There is no evidence to support discography without other non-invasive or less invasive modalities of treatments or other precision diagnostic injections.

Transforaminal Epidural Injections

The current evidence provides moderate evidence of transforaminal epidural injections in the preoperative evaluation of patients with negative or inconclusive imaging studies and clinical findings of nerve root irritation. The present review of the available literature provides limited evidence as to the role of transforaminal epidural injections in the diagnosis of segmental dural-nerve root pain in the absence of disc herniation and negative provocative discography.

Sacroiliac Joint Blocks

Based on the results of controlled diagnostic local anesthetic blocks, prevalence of sacroiliac joint pain has been shown to be present in 10% to 18.5% of patients with low back pain with a false-positive rate of 20%. The evidence for specificity and validity of sacroiliac joint diagnostic injections is moderate.

Therapeutic Interventional Techniques

Facet Joint Pain

- Intraarticular Injections. The evidence of intraarticular injections of local anesthetics and steroids from randomized trials, complemented with that of non-randomized trials (prospective and retrospective evaluations) provided moderate evidence of short-term relief and limited evidence of long-term relief of chronic neck and low back pain.
- Medial Branch Blocks. Combined evidence of the medial branch blocks from one randomized trial, complimented with two non-randomized trials (one prospective and one retrospective evaluation) provided strong evidence of short-term relief and moderate evidence of long-term relief of pain of facet joint origin.

- Medial Branch Neurotomy. Considering the one systematic review, two randomized trials, four prospective evaluations, and three retrospective evaluations, combined evidence of radiofrequency neurotomy of medial branches provided strong evidence of short-term relief and moderate evidence of long-term relief of chronic spinal pain of facet joint origin.

Epidural Injections

- Caudal Epidural Injections. The combined evidence of caudal epidural steroid injections with randomized trials and non-randomized trials (prospective and retrospective trials) is strong for short-term relief and moderate for long-term relief.
- Interlaminar Epidural Injections. Evidence for the overall effectiveness of interlaminar epidural steroid injections in managing chronic low back pain is moderate for short-term relief and limited for long-term relief.
- Transforaminal Epidural Injections. Based on the evaluation of multiple randomized and non-randomized trials, transforaminal epidural injections provided strong evidence for short-term and long-term relief. Their effectiveness in post lumbar laminectomy syndrome and disc extrusions is inconclusive.

Epidural Adhesiolysis

- Evidence of effectiveness of percutaneous adhesiolysis, based on randomized and non-randomized evaluations is moderate for short-term and long-term relief with repeat interventions.
- Evidence synthesis for spinal endoscopy with prospective evaluations and retrospective evaluations showed moderate evidence for short-term relief and limited evidence for long-term relief.

Intradiscal Therapies

- Intradiscal Electrothermal Therapy. Based on this evidence analysis, it appears that intradiscal electrothermal therapy meets the criteria for moderate evidence for short-term relief and limited evidence for long-term relief.
- Nucleoplasty. Evidence is limited showing the effectiveness of percutaneous disc decompression (PDD) with nucleoplasty.

Implantable Therapies

- Spinal Cord Stimulation. The evidence for spinal cord stimulation in properly selected population with neuropathic pain is moderate for long-term relief.
- Implantable Intrathecal Drug Administration System. Based on the available literature, there is moderate evidence indicating the long-term effectiveness of intrathecal infusion systems.

Evaluation

Appropriate history, physical examination, and medical decision making from the initial evaluation of a patient´s presenting symptoms are essential. There are

numerous acceptable medical methods to evaluate a chronic spinal pain patient. These methods vary from physician to physician and textbook to textbook. Following the guidelines established by the Centers for Medicare and Medicaid Services (CMS) not only would assist a physician in performing a comprehensive and complete evaluation, but also assist them to be in compliance with regulations. The guidelines of CMS provide various criteria for five levels of services. The three crucial components of evaluation and management services are: history, physical examination, and medical decision-making.

Evaluation and Management Algorithm

A suggested algorithm for the Comprehensive Evaluation and Management of Chronic Pain is available in the original guideline document (page 55).

Criteria for Performing Interventional Techniques

The following criteria should be considered carefully in performing interventional techniques:

- Complete initial evaluation, including history and physical examination.
- Physiological and functional assessment, as necessary and feasible.
- Definition of indications and medical necessity:
    - Suspected organic problem
    - Nonresponsiveness to less invasive modalities of treatments except in acute situations such as acute disc herniation, herpes zoster and postherpetic neuralgia, reflex sympathetic dystrophy, and intractable pain secondary to carcinoma.
    - Pain and disability of moderate-to-severe degree.
    - No evidence of contraindications such as severe spinal stenosis resulting in intraspinal obstruction, infection, or predominantly psychogenic pain.
    - Responsiveness to prior interventions with improvement in physical and functional status to proceed with repeat blocks or other interventions.
    - Repeating interventions only upon return of pain and deterioration in functional status.

Delivery of Interventional Technology

Following is the description of frequency of various types of interventional techniques. Safety and effectiveness of multiple types of interventional techniques have been established. These are based on available evidence and consensus to the safety, clinical effectiveness, and cost effectiveness. However, these are not based on evidence synthesis methodology. Descriptions are provided only for some commonly used procedures.

Facet Joint Injections

- In the diagnostic phase, a patient may receive injections at intervals of no sooner than 1 week or, preferably, 2 weeks.

- In the therapeutic phase (after the stabilization is completed), the suggested frequency would be 2 months or longer between each injection, provided that at least ≥50% relief is obtained for 6 weeks.
- If the neural blockade is applied for different regions, it can be performed at intervals of no sooner than 1 week or preferably 2 weeks for most types of blocks. It is suggested therapeutic frequency remain at 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- In the diagnostic or stabilization phase, the suggested number of injections would be limited to no more than 4 times per year.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria, and it is suggested that these be limited to a maximum of six times for local anesthetic and steroid blocks for a period of 1 year.
- Under unusual circumstances with a recurrent injury or cervicogenic headache, blocks may be repeated at intervals of 6 weeks after stabilization in the treatment phase.

Medial Branch Neurolysis

- The suggested frequency would be 3 months or longer between each neurolytic procedure, provided that at least ≥50% relief is obtained for 10 to 12 weeks.
- If the neural blockade is applied for different regions, it may be performed at intervals of no sooner than 1 week or, preferably, 2 weeks for most types of blocks. The therapeutic frequency for neurolytic blocks would preferably remain at intervals of at least 3 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.

Epidural Injections

- Epidural injections include caudal, interlaminar, and transforaminal.
- In the diagnostic phase, a patient may receive injections at intervals of no sooner than 1 week or preferably, 2 weeks, except for blockade in cancer pain or when a continuous administration of local anesthetic is employed for reflex sympathetic dystrophy.
- In the therapeutic phase (after the diagnostic phase is completed), the suggested frequency of interventional techniques would be 2 months or longer between each injection, provided that at least ≥50% relief is obtained for 6 to 8 weeks.
- If the neural blockade is applied for different regions, it may be performed at intervals of no sooner than 1 week and preferably 2 weeks for most type of blocks. The therapeutic frequency may remain at intervals at least 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- In the diagnostic phase, it is suggested number of injections would be limited to no more than 2 times except for reflex sympathetic dystrophy, in which case 3 times is reasonable.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria, and it is suggested that these be limited to a maximum of 6 times per year.

- Under unusual circumstances with a recurrent injury current injury, carcinoma, or reflex sympathetic dystrophy, blocks may be repeated at intervals of 6 weeks after diagnosis/stabilization in the treatment phase.

Percutaneous Lysis of Adhesions

- The number of procedures are preferably limited to:
    - With a 3-day protocol, 2 interventions per year,
    - With a 1-day protocol, 4 interventions per year.

Spinal Endoscopy

- The procedures are preferably limited to a maximum of 2 per year provided the relief was ≥50% for ≥4 months.

Sacroiliac Joint Injections

- In the diagnostic or stabilization phase, a patient may receive injections at intervals of no sooner than 1 week or, preferably, 2 weeks.
- In the treatment or therapeutic phase (after the stabilization is completed), the suggested frequency would be 2 months or longer between each injection, provided that at least ≥50% relief is obtained for 6 weeks.
- If the neural blockade is applied for different regions, it may be performed at intervals of no sooner than 1 week or, preferably, 2 weeks for most types of blocks. The therapeutic frequency may remain at 2 months for each region. It is further suggested that all regions be treated at the same time, provided all procedures are performed safely.
- In the diagnostic or stabilization phase, the suggested number of injections would be limited to no more than 4 times per year.
- In the treatment or therapeutic phase, the interventional procedures should be repeated only as necessary judging by the medical necessity criteria, and these should be limited to a maximum of 6 times for local anesthetic and steroid blocks for a period of 1 year.

Definitions:

Designation of Levels of Evidence

Level I

Conclusive: Research-based evidence with multiple relevant and high quality scientific studies or consistent reviews or consistent reviews of meta-analyses.

Level II

Strong: Research-based evidence from at least one properly designed randomized, controlled trial of appropriate size (with at least 60 patients in the smallest group); or research-based evidence from multiple properly designed studies of smaller size; or at least one randomized trial, supplemented by predominantly positive prospective and/or retrospective evidence.

Level III

Moderate: Evidence from a well-designed small randomized trial or evidence from well-designed trials without randomization, or quasi-randomized studies, single group, pre-post cohort, time series, or matched case-controlled studies or positive evidence from at least one meta-analysis.

Level IV

Limited: Evidence from well-designed nonexperimental studies from more than one center or research group.

Level V

Indeterminate: Opinions of respected authorities, based on clinical evidence, descriptive studies, or reports of expert committees.

CLINICAL ALGORITHM(S)

The original guideline contains algorithms for 1) the Comprehensive Evaluation and Management of Chronic Pain; 2) the Approach to Diagnosis of Chronic Back Pain without Disc Herniation; 3) the Application of Therapeutic Interventional Techniques in Management of Chronic Low Back Pain; and 4) the Approach to Diagnosis of Chronic Neck Pain without Disc Herniation.

EVIDENCE SUPPORTING THE RECOMMENDATIONS

TYPE OF EVIDENCE SUPPORTING THE RECOMMENDATIONS

The type of evidence supporting the recommendation is identified in the "Major Recommendations" field.

BENEFITS/HARMS OF IMPLEMENTING THE GUIDELINE RECOMMENDATIONS

POTENTIAL BENEFITS

- Recognition, assessment, treatment, and control of pain
- Improvement in function and quality of life
- Avoidance of possible toxic effects of therapy
- Alleviation of associated costs (e.g., healthcare expenditures, disability compensation, lost production, lost tax revenue)

POTENTIAL HARMS

Complications from diagnostic and therapeutic interventions are summarized briefly below. Please refer to the original guideline for a more detailed description of these complications.

Complications from diagnostic techniques

- Facet joint injections--dural puncture, spinal cord trauma, infection, intravascular injection, spinal anesthesia, chemical meningitis, neural trauma, pneumothorax, and hematoma formation. Also steroid side effects and radiation exposure.
- Discography procedures--infection, neural trauma, intravascular penetration, and spinal cord trauma.
- Transforaminal epidural injections--dural puncture, infection, vascular gas embolism, cerebral thrombosis, epidural hematoma, neural or spinal cord damage, and complications related to the administration of steroids.
- Sacroiliac joint injections--infection, trauma to the sciatic nerve, and other complications related to drug administration.

Complications from therapeutic techniques

- Percutaneous radiofrequency neurotomy--painful cutaneous dysesthesias, increased pain due to neuritis or neurogenic inflammation, anesthesia dolorosa, cutaneous hyperesthesia, pneumothorax and deafferentation pain.
- Adhesiolysis and spinal endoscopy--dural puncture, spinal cord compression, catheter shearing, infection, steroids, and more.
- Intradiscal electrothermal therapy (IDET)--catheter breakage, nerve root injury, post-IDET disc herniation, cauda equina syndrome.
- Spinal cord stimulation--correctable complications, such as lack of appropriate paraesthesia coverage to devastating complications, such as paralysis, nerve injury, and death.
- Intrathecal fusion systems--immediate complications, such as post-dural puncture headache, infection, nausea, urinary retention, and pruritus. Longer term complications include catheter and pump failure, and catheter granuloma.

CONTRAINDICATIONS

CONTRAINDICATIONS

Potential contraindications to diagnostic and therapeutic interventional techniques include:

- Bacterial infection
- Possible pregnancy
- Bleeding diathesis
- Anticoagulant therapy

QUALIFYING STATEMENTS

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- These guidelines do not constitute inflexible treatment recommendations. It is expected that a provider will establish a plan of care on a case-by-case basis, taking into account an individual patient´s medical condition, personal needs, and preferences, and the physician´s experience. Based on an individual patient´s needs, treatment different from that outlined here could be warranted. These guidelines do not represent "standard of care."

- Information included or excluded in this document is to be considered as a scholarly and scientific attempt to accurately reflect the best available knowledge. This document, therefore, stands as a work in progress. At no time should this document be construed as a defined pathway for treating chronic spinal pain, but a best attempt to provide rational interpretation of available data and add science to the art of interventional pain management. The scientific investigations inevitably will continue and contributions from authors and anecdotal sources are welcomed, encouraged, and assessed in an objective and scholarly environment. The authors encourage others to participate with further development of these guidelines. It is the intent of the authors of this document to be forthright, and to eliminate procedural, specialty, or practice bias.

  Thus, these guidelines are expected to be proactive, non-nihilistic and scientifically valid to the greatest extent possible.

IMPLEMENTATION OF THE GUIDELINE

DESCRIPTION OF IMPLEMENTATION STRATEGY

An implementation strategy was not provided.

INSTITUTE OF MEDICINE (IOM) NATIONAL HEALTHCARE QUALITY REPORT CATEGORIES

IOM CARE NEED

Living with Illness

IOM DOMAIN

Effectiveness
Patient-centeredness

IDENTIFYING INFORMATION AND AVAILABILITY

BIBLIOGRAPHIC SOURCE(S)

Manchikanti L, Staats PS, Singh V, Schultz DM, Vilims BD, Jasper JF, Kloth DS, Trescot AM, Hansen HC, Falasca TD, Racz GB, Deer TR, Burton AW, Helm S, Lou L, Bakhit CE, Dunbar EE, Atluri SL, Calodney AK, et al. Evidence-based practice guidelines for interventional techniques in the management of chronic spinal pain. Pain Phys 2003;6:3-81. [1175 references]

ADAPTATION

Not applicable: The guideline was not adapted from another source.

DATE RELEASED

2003

GUIDELINE DEVELOPER(S)

American Society of Interventional Pain Physicians - Medical Specialty Society

SOURCE(S) OF FUNDING

American Society of Interventional Pain Physicians

GUIDELINE COMMITTEE

Research and Guideline Committee

COMPOSITION OF GROUP THAT AUTHORED THE GUIDELINE

The Research and Guideline Committee was responsible for developing the guideline. It consisted of the Executive Committee of the Board and all the authors.

Primary Authors: Laxmaiah Manchikanti, MD; Peter S. Staats, MD; Vijay Singh, MD; David M. Schultz, MD; Bradley D. Vilims, MD; Joseph F. Jasper, MD; David S. Kloth, MD; Andrea M. Trescot, MD; Hans C. Hansen, MD; Thomas D. Falasca, DO; Gabor B. Racz, MD; Timothy R. Deer, MD; Allen W. Burton, MD; Standiford Helm, MD; Leland Lou, MD, MPH; Cyrus E. Bakhit, MD; Elmer E. Dunbar, MD; Sairam L. Atluri, MD; Aaron K. Calodney, MD; Samuel J. Hassenbusch, MD; Claudio A. Feler, MD

FINANCIAL DISCLOSURES/CONFLICTS OF INTEREST

There were no conflicts of financial interest. No funding was provided by any external agency.

GUIDELINE STATUS

This is the current release of the guideline.

GUIDELINE AVAILABILITY

Electronic copies: Available in Portable Document Format (PDF) from the American Society of Interventional Pain Physicians Web site.

Print copies: Available from the American Society of Interventional Pain Physicians, 2831 Lone Oak Road, Paducah, KY 42003; Phone: (270) 554-9412; Fax: (270) 554-8987; email: asipp@asipp.org.

AVAILABILITY OF COMPANION DOCUMENTS

None available

PATIENT RESOURCES

None available

NGC STATUS

This NGC summary was completed by ECRI on July 21, 2003. The information was verified by the guideline developer on July 31, 2003.

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